

Applicant(s): Bonutti et al.
Application No.: 10/626,951
Examiner: D. Doster-Greene

Remarks

Claims 1-8 are pending in the application and are presented for the Examiner's review and consideration. Claim 1 has been amended. Applicants believe the claim amendment and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. § 103(b)

Claims 1-8 were rejected under 35 U.S.C. §103(b) as being unpatentable over U.S. Patent No. 2,191,283 to Longfellow ("Longfellow") in view of U.S. Patent No. 5,385,539 to Burkhead *et al.* ("Burkhead").

In the Office Action, the Examiner asserted that:

Longfellow discloses a first drive assembly (35, 34, 36, 40) and a second drive assembly (37, 51, 55, 56, 57). The first drive assembly moves upper and lower sections of the orthosis relative to the base section about an axis which extends beneath an axilla of the patient's body. Shown in Fig. 1 in Longfellow, the upper arm section connects with an upper arm portion of the arm of the patient. The second drive assembly rotates the lower arm section and the lower portion of the arm of the patient about a second axis which extends through opposite ends of the upper portion of the arm of the patient and through a shoulder of the patient (Longfellow, col. 2, line 30-column 3, line 22).

For the reasons set forth below, Applicants respectfully submit that claim 1 is patentable over Longfellow in view of Burkhead.

Longfellow discloses improvements in splints utilized in the treatment of fractures which necessitate the holding of an upper limb in a fixed position with respect to the body. (Col. 1, lns. 2-5). Another objective of Longfellow is to provide an improved splint adaptable for mounting on either side of the patient's body and having parts . . . for securing the patient's upper arm and forearm in fixed positions with respect to the body. (Col. 1, lns. 13-20).

An upper arm support or cradle 20 is connected to the anchor member 1 by hinge 21 that

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is secured to the upper arm support or cradle 21 and the anchor member 1 by rivets 22, or other suitable means. (Col. 2, lns 5-9). A strut or brace comprising a turnbuckle 34 is fulcrumed at its ends . . . as at 35 and 36, to hinge brackets 37 and 38, respectively. (Col. 2, lns. 42-45). The angular relation between the upper arm and the body is adjusted by determining the position of the plate 39 with respect to the reinforcing strip and by adjustment of the turnbuckle 34. (Col. 3, lns. 66-71).

A forearm support strip 45 is adjustably secured at one end to the extension strip 31 by a bolt 46 which extends through an opening 47 in the forearm support strip 45 and through a longitudinal slot 48 in the extension strip 31 to provide a fulcrum for the forearm support strip 45; the forearm support strip 45 also being adjustable longitudinally of the extension strip 31 by movement of the bolt 46 in the slot 48. (Col. 3, lns. 11-19). A brace 50 is fulcrumed to the extension strip 31 and upper arm support of cradle 20 by a rivet 32 and has a longitudinal slot 51 therein. (Col. 3, lns. 23-25). The brace 50 is angularly disposed with respect to the extension strip 31 and forearm support strip 45 and is fulcrumed to the extension strip and adjustably secured to the forearm support strip 45 by wing bolt 52. (Col. 3, lns. 28-32).

When the wing bolt 52 and wing nut 49 are loosened, the forearm support strip is moved longitudinal of the extension strip 31 to effect adjustment corresponding to the length of the upper arm. (Col. 2, lns. 71-75). At the same time, the angular relation of the forearm with respect to the upper arm is determined by the angular adjustment of the forearm support strip 45. (Col 2, ln. 75 -col. 2. ln. 4). After such adjustment, the wing bolt and wing nut 49 are tightened to secure firmly the forearm support strip. (Col. 3, lns. 4-6).

In summary, Longfellow disclosed a splint utilized in the treatment of fractures which necessitate the holding of an upper limb in a fixed position with respect to the body. This is in contrast to the present invention which is directed to a method of effecting movement between bones in a patient's body.

Additionally, Longfellow discloses that the upper arm support is adjustable with respect to the body adjustment of the turnbuckle. An adjustment of the turnbuckle inherently provides a force between the upper arm section and the body to change the angular relationship thereof.

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The forearm support strip is adjustably connected to the upper arm support by means of a bolt in a slotted portion of the extension strip and a brace angularly disposed between the extension strip and the forearm support strip. The brace is adjustably secured to the forearm support strip by wing nut positioned through a slot in the brace. To adjust the angular relationship between the forearm support strip and the extension strip, the bolt and wing nut are loosened, allowing the movement with the slots in the extension strip and the brace. However, Longfellow does not disclose a drive mechanism connected between the forearm support strip and the extension strip for provided a force to effect relative movement between the forearm support strip and the extension strip.

As noted above, the angular relationship between the forearm support strip and the extension strip is adjustable. Such a change in the angular relationship changes the angular relationship of the forearm with respect to the upper arm. However, such an adjustment does not rotate the upper arm, humerus bone, about its central axis.

Referring to Figs. 1-3 of Longfellow, the forearm support strip and extension strip define a plane through which the forearm is moved. As shown in FIG. 2, the upper arm support also lies in that plane. As such, as the forearm support strip is rotated with respect to the extension strip, the forearm support strip is rotated about an axis orthogonal to the defined plane. As a consequence, the planar movement of the forearm support strip with respect to the extension strip only moves the forearm with respect to the upper arm, without a rotation of the upper arm about its central axis. For the upper arm to be rotated about its central axis as the forearm support strip is rotated with respect to the extension strip, the rotation of the forearm support with respect to the extension strip would have to be non-planar to that of the upper arm. Such a rotation is not disclosed in Longfellow.

Burkhead discloses an orthopedic device for immobilizing and supporting limbs of a patient. (Col. 1, lns. 6-8). The orthopedic brace 10 consists of a harness 12, an arm support assembly 14, and a positioning assembly 16. (Col. 2, lns. 62-64). The positioning assembly 16 includes a positioning rod 28, an upper universal joint 30, a lower universal joint 32, and an adjustable mounting assembly 34. (Col. 3, lns. 17-20). The upper universal joint end plate 84 is

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attached to the upper end of the forearm support bar 88, which is in turn attached to the lower end of upper arm support bar 86 by a screw (not shown) threaded into the upper end of upper ball arm 82. (Col. 4, Ins. 25-30). The relative angular orientation ϕ of the support bars 86, 88 is determined by the insertion of an elbow angle set pin 92 into one of multiple adjustment holes 94. (Col. 4, Ins. 30-34).

Similar to Longfellow, the angular relationship between the forearm support bar and the upper arm support bar is adjustable. Such a change in the angular relationship changes the angular relationship of the forearm with respect to the upper arm. However, such an adjustment does not rotate the upper arm, humerus bone, about its central axis. Additionally, the rotation of the forearm support bar with the upper arm support bar is about axis perpendicular to a plane defining the forearm support bar and the upper arm support bar. As such, the combination of Burkhead with Longfellow does not eliminate the above-noted deficiencies.

In contrast, the present invention discloses an apparatus for effecting movement of bones in an arm of a patient relative to a shoulder of the patient. ([0002]). A drive assembly is operable to rotate the first cuff and humerus bone in the arm of the patient about a central axis of the humerus bone. ([0006]).

A shoulder brace or orthosis 10 (FIGS. 1-3) effects relative movement between bones in a body 12 (FIG. 1) of a patient 14. ([0017]). The shoulder orthosis 10 includes a base section 30 (FIGS. 1-3) which is connected with a trunk 32 (FIG. 1) of the patient's body. ([0018]). The shoulder orthosis 10 includes an upper arm section 38 (FIGS. 1-3) which is connected with the upper arm section 40 (FIG. 1) of the left arm 20 of the patient and a lower arm section 42 (FIGS. 1-3) of the shoulder orthosis 10 which is connected with a lower arm section 44 (FIG. 1) of the left arm 20 and hand 46 of the patient 14. ([0019]).

A main drive assembly 50 (FIGS. 1-3) interconnects the upper arm section 38 and the lower arm section 42. ([0020]). Operation of the main drive assembly 50 rotates the bones in the arm 20 of the patient 14 about a longitudinal central axis of the upper arm section 40. ([0021]). The main drive assembly 50 (FIG. 1) is constructed so that it continuously transmits force and is not operated in a reverse direction upon interruption of operation of the main drive assembly by

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the patient 14. ([0026]).

As such, the present invention discloses a method of using an orthosis to rotate the bones in an arm of a patient. The orthosis includes upper and lower arm section for connecting to the upper and lower arm portions of the patient. A main drive assembly interconnects the upper and lower arm sections. The main drive assembly provides a continuous force to rotate the bones in the arm about a longitudinal central axis of the upper arm.

Amended claim 1 recites, *inter alia*, a method of effecting movement between bones in a patient's body. The method includes positioning a base section of an orthosis in proximal relation with a trunk of the patient's body. A first drive assembly is operated to move upper and lower arm sections of the orthosis relative to the base section about an axis which extends beneath an axilla of the patient's body. The upper arm section of the orthosis is connected with an upper portion of the arm of the patient and the lower section of the orthosis is connected with a lower portion of the arm of the patient. A second drive assembly is operated to rotate the lower arm section and the lower portion of the arm of the patient about a second axis which extends through opposite ends of the upper portion of the arm of the patient and through a shoulder of the patient. The second drive assembly provides a force to the lower arm section and lower portion of the arm of the patient.

In light of the foregoing, independent claim 1 is respectfully submitted to be patentable over Longfellow in view of Burkhead. As claims 2-8 depend from claim 1, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicants respectfully submit that dependent claims 2-8 are allowable over Longfellow in view of Burkhead at least for the same reasons.

Double Patenting

Claim 1 was rejected under the judicially created doctrine of double patenting over claim 30 of US Patent No. 6,599,263, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

In response and in order to expedite the prosecution of this application, Applicants submit

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herewith a Terminal Disclaimer to obviate these double patenting rejections. It should be understood that this Terminal Disclaimer is being filed to expedite prosecution and should not be construed as an admission that the Terminal Disclaimer is necessary.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$55.00 for the accompanying Terminal Disclaimer is believed to be due and a Fee Transmittal Sheet with payment by credit card is submitted concurrently herewith. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 781-A02-006-2).

Respectfully submitted,



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